

MINUTES
KENTUCKY BOARD OF PHARMACY
Frankfort, Kentucky
December 8, 2004

CALL TO ORDER: A regular meeting of the Kentucky Board of Pharmacy was held at the Board office, 23 Millcreek Park, in Frankfort, Kentucky. President Armstrong called the meeting to order at 9:15 a.m.

Members present: Tim Armstrong, Becky Cooper, Mark Edwards, Georgina Kindall Jones, Greg Naseman, and Patricia Thornbury. Staff present: Michael Burleson, Executive Director; Jeffery L. Osman, Inspections and Investigations Coordinator; Katie Busroe, Steve Hart, and Phil Losch, Pharmacy and Drug Inspectors; and Cheryl Lalonde-Mooney, Assistant Attorney General and Board Counsel. Guests: Brian Fingerson, Pharmacist Recovery Network; Paula York, Drug Enforcement and Professional Practices Branch of the Cabinet for Health and Family Services; Mike Mayes and Joel Thornbury, Kentucky Pharmacists Association; Tera McIntosh, American Pharmacy Services Corporation; Jan Gould, Kentucky Retail Federation; Todd Downing, CVS Pharmacies; Sue Gage, Target Pharmacies; Jeff Mills, Chad Downing, and Greg Baker, Walgreens Pharmacies; Matt Miles and Kevin Lamping, Rite Aid Pharmacies; Jody Jagers, Aaron Kirkpatrick, Brian Lucas, Ashley McNeil, and Adam Parrish, University of Kentucky College of Pharmacy intern students; Pete Orzali; Maxine Snively; and Bill Thornbury. Juanita O'Toole, Court Reporter, recorded the meeting.

MINUTES: On motion by Ms. Jones, seconded by Mr. Edwards and passed unanimously, the Minutes of November 13, 2004 were adopted.

INTERAGENCY: **Drug Enforcement and Professional Practices Branch of the Cabinet for Health and Family Services/Paula York.** Ms. York informed the Board of a policy update by the Drug Enforcement Administration (DEA). In August 2004, DEA published on its Office of Diversion Control web site a document entitled: "Prescription Pain Medications: Frequently Asked Questions and Answers for Health Care Professionals and Law Enforcement Personnel." In response to a question about refilling Schedule II prescriptions the statement was made that, "Schedule II prescriptions may not be refilled; however, a physician may prepare multiple prescriptions on the same day with instructions to fill on different dates." In a clarification published in the Federal Register the following statement appears: "No prescription for a controlled substance in Schedule II may be refilled, 21 U.S.C. 829(a). For a physician to prepare multiple prescriptions on the same day with instructions to fill on different dates is tantamount to writing a prescription authorizing refills of a Schedule II controlled substance. To do so conflicts with one of the fundamental purposes of section 829(a)." Prescribers may no longer write Schedule II prescriptions with instructions to fill at a later date and dispensers may no longer accept such prescriptions. Ms. York asked the Board to help disseminate this information to the pharmacists of Kentucky. Ms. Thornbury moved for Mr. Burleson to draft a letter of concern to the DEA regarding this policy. The rural nature of the Commonwealth makes it difficult for many citizens to obtain health care

and this ruling by DEA may prove a hardship for many patients on chronic Scheduled II controlled substance drug therapy. Furthermore, the alternatives to writing instructions to fill at a later date on a Scheduled II controlled substance prescription may increase diversion, already a problem in Kentucky. Ms. Jones seconded and the motion passed unanimously.

BOARD REPORTS: **President.** Mr. Joel Thornbury presented President Armstrong with the President's Award from the Kentucky Pharmacists Association (KPhA) and thanked President Armstrong for his hard work and dedication to the profession of pharmacy. He also presented President Armstrong with a signed program from the Board of Pharmacy Retreat in 2004 and thanked the Kentucky Board of Pharmacy for allowing KPhA to cosponsor the Retreat.

1. **Advisory Council.** Ms. Thornbury moved to appoint Tim Armstrong to serve as chairperson and interim President of the Advisory Council, with the determination of who will serve on the Advisory Council to be made at a later date. Ms. Kindall Jones seconded and the motion passed unanimously. Ms. Thornbury moved that Tim Armstrong's term on the Advisory Council not be effective immediately, but start at the same time as all the other appointments so that all 4 year terms end simultaneously. Ms. Cooper seconded and the motion passed unanimously. A list of names of interested persons was distributed to the Board members.
2. **Recognize Maxine Snively.** President Armstrong thanked Ms. Snively for her work and dedication to the Board office and presented her with a mortar and pestle from Louisville Stoneware.
3. **Welcome Pete Orzali, Jr.** President Armstrong welcomed new Board appointee Mr. Orzali. Mr. Orzali was sworn in by Dr. Osman.
4. **Welcome Steve Hart.** President Armstrong welcomed Mr. Hart as the new Pharmacy and Drug Inspector.
5. **Review of 2004 Accomplishments.** (A) A new Executive Director was hired.
(B) A new Pharmacy and Drug Inspector was hired.
(C) Darla Sayre is doing a fantastic job as the Administrative Specialist III.
(D) Legislatively the term limits of the Board members was extended to 4 years and pharmacist administered immunizations statutes were updated.
(E) Over the last several years the Board has made an effort to establish good working relationships with sister agencies in the state.
(F) The office is in very good shape, with telephone and computer systems being updated.
6. **Election of President-Elect 2005.** Mr. Naseman and Ms. Thornbury were nominated for the office of President-Elect. Mr. Naseman was elected President-Elect via secret ballot.
7. **Friend of Board of Pharmacy 2004 Award.** President Armstrong presented Dr. Ralph Bouvette, in absentia, the Friend of the Board of Pharmacy 2004 Award.
8. **Board Exams January 22, 2005.** The Board was reminded of the date of the January 2005 Board Exam and was asked to turn in material for the exam as soon as possible.

Ms. Thornbury. Ms. Thornbury gave an update on the New Board Member Manual Committee. Ms. Thornbury had met with Mr. Burleson and Ms. Lalonde-Mooney and the Manual has been completely reworked. Mr. Orzali will have the most current information available. Ms. Thornbury thanked Ms. Lalonde-Mooney for her help with the Manual.

Executive Director. Mr. Edwards moved to approve Donald S. Wede's request to reciprocate. Ms. Jones seconded and the motion passed unanimously.

Mr. Edwards moved for approval of the following dates for the Impaired Pharmacist Committee meetings: February 22, 2005 at 10:00 a.m.

March 29, 2005 at 10:00 a.m.

May 17, 2005 at 10:00 a.m.

June 28, 2005 at 10:00 a.m.

August 30, 2005 at 10:00 a.m.

September 20, 2005 at 10:00 a.m.

November 29, 2005 at 10:00 a.m.

and the following dates for the Case Review Committee meetings:

February 22, 2005 at 1:00 p.m.

March 29, 2005 at 1:00 p.m.

May 17, 2005 at 1:00 p.m.

June 28, 2005 at 1:00 p.m.

August 30, 2005 at 1:00 p.m.

September 20, 2005 at 1:00 p.m.

November 29, 2005 at 1:00 p.m.

Ms. Jones seconded and the motion passed unanimously.

Ms. Jones moved to set the attendance for the following out of state meetings: 1. American Pharmacist Association Meeting: Mr. Edwards and Mr. Burleson. 2. National Association of Boards of Pharmacy (NABP) Meeting: entire Board and staff including counsel. 3. NABP District III Meeting: entire Board and staff including counsel. 4. University of Utah School on Alcoholism and Other Drug Dependencies: Mr. Burleson, Mr. Naseman, Ms. Thornbury, one staff, with Mr. Orzali as an alternate. 5. National Community Pharmacists Association Meeting: Ms. Thornbury. 5. NABP Review: Mr. Burleson. Ms. Cooper seconded and the motion passed unanimously.

IPC Chairman. Mr. Edwards moved for the Board to approve one committee member from the IPC to attend the CAPTASA conference. Mr. Naseman seconded and the motion passed unanimously.

CURRENT/PENDING CASES: Mr. Edwards moved for acceptance and entry of the proposed Agreed Orders as written. Mr. Naseman seconded and the motion passed with Ms. Jones recusing herself from Case No. 04-0040.

Case No. 02-0059; Case No. 02-0139A; Case No. 03-0125A; Case No. 03-0141B; Case No. 03-0142; Case No. 03-0148A; Case No. 03-0148B; Case No. 03-0148C; Case No.

03-0152; Case No. 03-0153; Case No. 03-0154; Case No. 04-0006; Case No. 04-0021; Case No. 04-0029A; Case No. 04-0029B; Case No. 04-0040; Case No. 04-0051A; Case No. 04-0051B; Case No. 04-0053B; Case No. 04-0064; Case No. 04-0070G; Case No. 04-0070J; Case No. 04-0070M; Case No. 04-0071A; Case No. 04-0071B; Case No. 04-0073A; Case No. 04-0073B; Case No. 04-0074; Case No. 04-0078A; Case No. 04-0079; Case No. 04-0083; Case No. 04-0084.

CASE REVIEW COMMITTEE: Mr. Edwards moved for acceptance of the Committee recommendation for the following case reports.

Case No. 02-0105 Revisit. Pharmacy Corporation is allegedly consistently misbranding by mislabeling all prescriptions written by advanced registered nurse practitioners and physician's assistants as "DR" for an extended period of time after being informed of the violation. The Board office informed the pharmacy corporation August 2, 2001, that the prescription label needed to reflect the correct designation of the prescriber, since it appeared that every prescriber was labeled as Dr. even if it was an advanced registered nurse practitioner or a physician's assistant. As of June 13, 2002, the pharmacy corporation had not corrected the prescriber designation. Alleged violation of law: KRS 217.065 (1). Case Review Committee recommended a 4, an attempt to resolve through an Agreed Order at the September 10, 2002, Case Review Committee meeting. The Board affirmed the recommendation at the September 11, 2002, meeting of the Kentucky Board of Pharmacy. CRC recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Ms. Cooper seconded and the motion passed unanimously.

Case No. 03-0118 Revisit. Pharmacist/doctor of osteopathic medicine had medical license revoked in the Commonwealth of Kentucky due to violations of controlled substances laws, including inappropriate prescribing of controlled substances. Alleged violations of law: KRS 315.121(1)(a) and (2)(a)(d)(e). Case Review Committee recommended a 4, an attempt to resolve through an Agreed Order at the October 7, 2003, Case Review Committee meeting. The Board affirmed the recommendation at the October 8, 2003, meeting of the Kentucky Board of Pharmacy. CRC recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Ms. Cooper seconded and the motion passed unanimously.

Case No. 04-056A. Pharmacy permit holder allegedly sold a misbranded product as the result of a medication error. The Board office received a complaint from the Medicaid/Welfare Fraud and Abuse Hotline. The patient reported that the prescription was telephoned to the pharmacy for permethrin 5% cream but filled as permethrin 1% cream rinse and labeled as the 5% cream. The pharmacy also billed Medicaid \$26.69 when the cost of the permethrin 1% cream rinse was \$7.00. Alleged violation of law: KRS 217.065(1). CRC recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution

through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Ms. Cooper seconded and the motion passed unanimously.

Case No. 04-056B. Pharmacist allegedly engaged in unprofessional conduct by committing a medication error. The Board office received a complaint from the Medicaid/Welfare Fraud and Abuse Hotline. The patient reported that the prescription was telephoned to the pharmacy for permethrin 5% cream but filled as permethrin 1% cream rinse and labeled as the 5% cream. The pharmacy also billed Medicaid \$26.69 when the cost of the permethrin 1% cream rinse was \$7.00. Alleged violation of law: KRS 315.121(2)(d). CRC recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Ms. Cooper seconded and the motion passed unanimously.

Case No. 04-057A. Pharmacy permit holder allegedly sold misbranded products as the result of medication errors in the form of miscounted prescriptions. The Board office received a complaint from the Medicaid/Welfare Fraud and Abuse Hotline. The patient reported on two separate occasions she was shorted tablets, once on Xanax and once on Vicoden ES. The pharmacist counts the prescriptions more than once and the prescriptions were not billed to Medicaid. Alleged violation of law: KRS 217.065(1). CRC recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Ms. Cooper seconded and the motion passed unanimously.

Case No. 04-057B. Pharmacist allegedly engaged in unprofessional conduct by committing medication errors in the form of miscounted prescriptions. The Board office received a complaint from the Medicaid/Welfare Fraud and Abuse Hotline. The patient reported on two separate occasions she was shorted tablets, once on Xanax and once on Vicoden ES. The pharmacist counts the prescriptions more than once and the prescriptions were not billed to Medicaid. Alleged violation of law: KRS 315.121(2)(a). CRC recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Ms. Cooper seconded and the motion passed unanimously.

Case No. 04-065. Pharmacist allegedly self prescribed and dispensed several medications including at least one controlled substance, without physician authorization. Pharmacist was arrested by police and charged with filling multiple prescriptions without authorization from a licensed prescriber. The drugs in question are Cialis, Lotrel, furosemide, Zithromax, ketaconazole, Patanol, Zyrtec, metformin, dexamethasone, aluminum cl, and Provigil (a Scheduled IV controlled substance). Pharmacist did plead guilty to one felony count conviction in Jefferson Circuit Court. The charge pertained to the drug Provigil and was “obtaining drugs by fraud and deceit.” The sentence was placement into a three year diversion program, that will be set aside and held for naught. Alleged violations of law: KRS 315.121(1)(c)1 and KRS 315.121(2)(e) and (f). CRC

recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Ms. Cooper seconded and the motion passed unanimously.

Case No. 04-075. Pharmacist allegedly engaged in unprofessional and unethical conduct by selling misbranded drugs. Pharmacist has admitted to an FDA agent that he was selling physician's samples to at least four pharmacies, using physician's samples in at least two pharmacies he owned, buying and taking samples from physicians' offices, and has surrendered his Kentucky pharmacist's license. The FDA agent has requested that he be allowed to complete all subsequent investigations before the Kentucky Board of Pharmacy take any action against pharmacists or pharmacies. Alleged violations of law: KRS 217.065 and KRS 315.121(2)(d)(e)(f). CRC recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation. Ms. Cooper seconded and the motion passed unanimously.

Case No. 04-080A. Pharmacy allegedly sold a misbranded product as the result of a medication error. A prescription was presented for Depakote 500 mg tablets, quantity 120. The pharmacy only had 110 tablets in stock. One pharmacist dispensed the 110, owing the patient 10 tablets. A second pharmacist, reprinted the original label, having the first pharmacist's initials on it, and filled the remaining 10 tablets as Depakote ER 500 mg. The 10 Depakote ER 500 mg tablets were delivered to the patient's home but the patient's mother recognized that it was not the correct medication, therefore, the patient did not receive any of the incorrect drug. Alleged violation of law: KRS 217.065. CRC recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Ms. Cooper seconded and the motion passed unanimously.

Case No. 04-080B. Pharmacist allegedly engaged in unprofessional conduct by committing a medication error. A prescription was presented for Depakote 500 mg tablets, quantity 120. The pharmacy only had 110 tablets in stock. One pharmacist dispensed the 110, owing the patient 10 tablets. A second pharmacist, reprinted the original label, having the first pharmacist's initials on it, and filled the remaining 10 tablets as Depakote ER 500 mg. The 10 Depakote ER 500 mg tablets were delivered to the patient's home but the patient's mother recognized that it was not the correct medication, therefore, the patient did not receive any of the incorrect drug. Alleged violation of law: KRS 315.121(2)(d). CRC recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Ms. Cooper seconded and the motion passed unanimously.

Case No. 04-081A. Special limited medical gas pharmacy permit holder allegedly failed to renew permit in a timely manner and continued to operate as a special limited medical gas pharmacy. The permit expired at the close of business on June 30, 2004, and the Board office received the renewal application on September 30, 2004. Alleged violation of law: KRS 315.035. CRC recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Ms. Cooper seconded and the motion passed unanimously.

Case No. 04-081B. Pharmacist consultant for a special limited medical gas pharmacy permit holder allegedly failed to renew permit in a timely manner and continued to operate as a special limited medical gas pharmacy. The permit expired at the close of business on June 30, 2004, and the Board office received the renewal application on September 30, 2004. Alleged violation of law: KRS 315.035. CRC recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Ms. Cooper seconded and the motion passed unanimously.

Case No. 04-082. Wholesale permit holder allegedly relocated without notifying the Board office. Permit holder moved around the first part of September 2004, and wrote the new address on the permit renewal application that was received at the Board office on September 28, 2004. Alleged violations of law: KRS 315.036(1) and 201 KAR 2:050 Section (1)(13). CRC recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Ms. Cooper seconded and the motion passed unanimously.

Case No. 04-085A. Pharmacy permit holder allegedly dispensed a misbranded product as the result of a medication error and allegedly failed to maintain accurate computerized records. The Board office received a written complaint and pending case from the Ohio Board of Pharmacy. A patient in an Ohio long term care facility received a medication for which she had a documented allergy in both the patient's chart at the facility and in the pharmacy computer. The patient ultimately died with the death certificate stating that the death was due to cardiorespiratory failure possibly due to or as a consequence of 3 underlying conditions including but not limited to a possible allergic reaction to this drug. The computer system did not hard halt the pharmacist with the allergy, but the data entry screen had in red "note resident allergies." The pharmacist had to manually toggle to another screen and review any allergies. The pharmacist working this day was not in the pharmacy computer system and practiced using the pharmacist-in-charge's initials and passwords. The Ohio investigation also revealed that this same patient was dispensed Procardia despite a documented allergy to this drug also. This allergy was later removed. Furthermore, the original prescription was written for Procardia 30 mg but the pharmacy

dispensed Procardia XL 30 mg. Alleged violations of law: KRS 217.065(1) and 201 KAR 2:170 Section 1 (2)(h). CRC recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Ms. Cooper seconded and the motion passed unanimously.

Case No. 04-085B. Pharmacist-in-charge allegedly failed to maintain accurate computerized records. The Board office received a written complaint and pending case from the Ohio Board of Pharmacy. A patient in an Ohio long term care facility received a medication for which she had a documented allergy in both the patient's chart at the facility and in the pharmacy computer. The patient ultimately died with the death certificate stating that the death was due to cardiorespiratory failure possibly due to or as a consequence of 3 underlying conditions including but not limited to a possible allergic reaction to this drug. The computer system did not hard halt the pharmacist with the allergy, but the data entry screen had in red "note resident allergies." The pharmacist had to manually toggle to another screen and review any allergies. The pharmacist working this day was not in the pharmacy computer system and practiced using the pharmacist-in-charge's initials and passwords. The Ohio investigation also revealed that this same patient was dispensed Procardia despite a documented allergy to this drug also. This allergy was later removed. Furthermore, the original prescription was written for Procardia 30 mg but the pharmacy dispensed Procardia XL 30 mg. Alleged violation of law: 201 KAR 2:170 Section 1 (2)(h). CRC recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Ms. Cooper seconded and the motion passed unanimously.

Case No. 04-085C. Pharmacist allegedly engaged in unprofessional conduct by committing a medication error and failing to perform a prospective drug utilization review. The Board office received a written complaint and pending case from the Ohio Board of Pharmacy. A patient in an Ohio long term care facility received a medication for which she had a documented allergy in both the patient's chart at the facility and in the pharmacy computer. The patient ultimately died with the death certificate stating that the death was due to cardiorespiratory failure possibly due to or as a consequence of 3 underlying conditions including but not limited to a possible allergic reaction to this drug. The computer system did not hard halt the pharmacist with the allergy, but the data entry screen had in red "note resident allergies." The pharmacist had to manually toggle to another screen and review any allergies. The pharmacist working this day was not in the pharmacy computer system and practiced using the pharmacist-in-charge's initials and passwords. The Ohio investigation also revealed that this same patient was dispensed Procardia despite a documented allergy to this drug also. This allergy was later removed. Furthermore, the original prescription was written for Procardia 30 mg but the pharmacy dispensed Procardia XL 30 mg. Alleged violations of law: KRS 315.121(2)(d) and 201 KAR 2:210 Section 4 (1) and (3)(a). CRC recommendation: There is sufficient evidence

of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Ms. Cooper seconded and the motion passed unanimously.

Case No. 04-086A. Pharmacy Corporation allegedly engaged in unprofessional and unethical conduct by knowing that a pharmacist was engaged in the unlawful distribution of legend medications and failed to report any relevant information to the Board. The Board office was notified that a pharmacist was refilling prescriptions that did not have any refills remaining and/or filling refills after the original prescription had expired. A coworker had notified the pharmacy corporation of this practice and the corporation did investigate, but claimed they were unable to find evidence to support the allegation. The pharmacist had been engaging in this practice since at least 2001. Alleged violation of law: KRS 315.121(1)(j). CRC recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Ms. Cooper seconded and the motion passed unanimously.

Case No. 04-086B. Pharmacist allegedly engaged in unprofessional and unethical conduct by dispensing drugs for which prescription drug orders are required without having first received authorization from a licensed practitioner. The Board office was notified that a pharmacist was refilling prescriptions that did not have any refills remaining and/or filling refills after the original prescription had expired. A coworker had notified the pharmacy corporation of this practice and the corporation did investigate, but claimed they were unable to find evidence to support the allegation. The pharmacist had been engaging in this practice since at least 2001. Alleged violation of law: KRS 315.121(2)(f). CRC recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Ms. Cooper seconded and the motion passed unanimously.

Case No. 04-086C. Pharmacist supervisor allegedly engaged in unprofessional and unethical conduct by not being truthful with a Pharmacy and Drug Inspector about a complaint. The complaint was regarding a pharmacist dispensing drugs for which prescription drug orders are required without having first received authorization from a licensed practitioner. The Board office was notified that a pharmacist was refilling prescriptions that did not have any refills remaining and/or filling refills after the original prescription had expired. A coworker had notified the pharmacy corporation of this practice and the corporation did investigate, but claimed they were unable to find evidence to support the allegation. The pharmacist had been engaging in this practice since at least 2001. Alleged violation of law: KRS 315.121(2)(f). CRC recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the

issuance of a Formal Complaint and Notice of Hearing. Ms. Cooper seconded and the motion passed unanimously.

Case No. 04-087. Pharmacy permit holder allegedly failed to notify the Board office of a change in pharmacist-in-charge (PIC). The PIC of record at the Board office has not worked at this pharmacy since July 7, 2004. Alleged violation of law: 201 KAR 2:205 Section 2(3)(d). CRC recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Ms. Cooper seconded and the motion passed unanimously.

Case No. 04-088A. Pharmacy permit holder allegedly failed to have in place proper security of controlled substances. Approximately 7300 dosage units of controlled substances were diverted by the employee daughter of the pharmacist owner. Missing were approximately 7200 dosage units of hydrocodone/acetaminophen and 100 dosage units of methadone. Alleged violation of law: 201 KAR 2:205 Section 2(3)(b). CRC recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Ms. Cooper seconded and the motion passed unanimously.

Case No. 04-088B. Pharmacist-in-charge allegedly failed to have in place proper security of controlled substances. Approximately 7300 dosage units of controlled substances were diverted by the employee daughter of the pharmacist owner. Missing were approximately 7200 dosage units of hydrocodone/acetaminophen and 100 dosage units of methadone. Alleged violation of law: 201 KAR 2:205 Section 2(3)(b). CRC recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Ms. Cooper seconded and the motion passed unanimously.

Case No. 04-089. Manufacturer permit holder allegedly failed to renew permit in a timely manner and continued to operate. The permit expired at close of business on September 30, 2004, and the Board office received the renewal application on October 1, 2004. Alleged violations of law: KRS 315.036 (1) and 201 KAR 2:050 Section (1)(15). CRC recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Ms. Cooper seconded and the motion passed unanimously.

Case No. 04-090A. Special limited medical gas pharmacy permit holder allegedly failed to renew permit in a timely manner and continued to operate as a special limited medical

gas pharmacy. The permit expired at close of business on June 30, 2004, and the Board office received the renewal application on September 27, 2004. Alleged violations of law: KRS 315.035 and 201 KAR 2:050. CRC recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Ms. Cooper seconded and the motion passed unanimously.

Case No. 04-090B. Pharmacist consultant of a special limited medical gas pharmacy permit allegedly failed to renew permit in a timely manner and permit holder continued to operate as a special limited medical gas pharmacy. The permit expired at close of business on June 30, 2004, and the Board office received the renewal application on September 27, 2004. Alleged violations of law: KRS 315.035 and 201 KAR 2:050. CRC recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Ms. Cooper seconded and the motion passed unanimously.

Case No. 04-091. Wholesale permit holder allegedly failed to renew permit in a timely manner and continued to operate as a wholesaler. The permit expired at close of business on September 30, 2004, and the Board office received the renewal application on October 14, 2004. Alleged violations of law: KRS 315.036(1) and 201 KAR 2:050 Section (1)(15). CRC recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Ms. Cooper seconded and the motion passed unanimously.

Case No. 04-092A. Pharmacy permit holder allegedly sold a misbranded product as the result of a medication error. The Board office received a Medical Liability Insurance report from the Kentucky Department of Insurance. On July 19, 2003, a patient presented a refill for clonidine. The prescription was filled with clonazepam. The patient took the incorrect medication and was hospitalized for several days. Alleged violation of law: KRS 217.065(1). CRC recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Ms. Cooper seconded and the motion passed unanimously.

Case No. 04-092B. Pharmacist allegedly engaged in unprofessional conduct by committing a medication error. The Board office received a Medical Liability Insurance report from the Kentucky Department of Insurance. On July 19, 2003, a patient presented a refill for clonidine. The prescription was filled with clonazepam. The patient took the incorrect medication and was hospitalized for several days. Alleged violation of

law: KRS 315.121(2)(d). CRC recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Ms. Cooper seconded and the motion passed unanimously.

Case No. 04-094. Pharmacist allegedly engaged in unprofessional conduct by committing a medication error. The Board office received a Medical Liability Insurance report from the Kentucky Department of Insurance. The patient had been on clonidine and clonazepam previously. The patient's mother indicated that the patient was allergic to clonazepam and requested that any further refills for clonazepam be deleted from the patient's profile. On or about May 25, 2004, the patient was staying with his father and the father requested a refill for clonidine but the refill for clonazepam was dispensed. The prescription information regarding this incident could not be located. This pharmacist assumed all responsibility for the medication error. The pharmacy had an ownership change on July 15, 2004. Alleged violation of law: KRS 315.121 (2)(d). CRC recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Ms. Cooper seconded and the motion passed unanimously.

Case No. 04-097A. Pharmacy permit holder allegedly sold misbranded drugs. An FDA agent has conducted an investigation regarding pharmacies buying and selling physician's samples. Approximately 3 years ago, the pharmacist-in-charge (PIC) paid an estimated \$250.00 for a tote of drugs in plastic bags, presumed to be samples. Over a year period the PIC dispensed a few of the drugs. The FDA agent has requested that he be allowed to complete all subsequent investigations before the Kentucky Board of Pharmacy take any action against pharmacists or pharmacies. Alleged violation of law: KRS 217.065. CRC recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation. Ms. Cooper seconded and the motion passed unanimously.

Case No. 04-097B. Pharmacist-in-charge (PIC) allegedly sold misbranded drugs. An FDA agent has conducted an investigation regarding pharmacies buying and selling physician's samples. Approximately 3 years ago, the PIC paid an estimated \$250.00 for tote of drugs in plastic bags, presumed to be samples. Over a year period the PIC dispensed a few of the drugs. The FDA agent has requested that he be allowed to complete all subsequent investigations before the Kentucky Board of Pharmacy take any action against pharmacists or pharmacies. Alleged violation of law: KRS 217.065. CRC recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation. Ms. Cooper seconded and the motion passed unanimously.

Case No. 04-098A. Pharmacy permit holder allegedly sold misbranded drugs. An FDA agent has conducted an investigation regarding pharmacies buying and selling

physician's samples. Over an eighteen month period, the pharmacist-in-charge (PIC) paid an estimated \$30,000.00 for physician's samples delivered in plastic freezer bags. The transactions stopped in July 2004 at the onset of an investigation and any sample drug inventory was destroyed. The FDA agent has requested that he be allowed to complete all subsequent investigations before the Kentucky Board of Pharmacy take any action against pharmacists or pharmacies. Alleged violation of law: KRS 217.065. CRC recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation. Ms. Cooper seconded and the motion passed unanimously.

Case No. 04-098B. Pharmacist-in-charge (PIC) allegedly sold misbranded drugs. An FDA agent has conducted an investigation regarding pharmacies buying and selling physician's samples. Over an eighteen month period, the PIC paid an estimated \$30,000.00 for physician's samples delivered in plastic freezer bags. The transactions stopped in July 2004 at the onset of an investigation and any sample drug inventory was destroyed. The FDA agent has requested that he be allowed to complete all subsequent investigations before the Kentucky Board of Pharmacy take any action against pharmacists or pharmacies. Alleged violation of law: KRS 217.065. CRC recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation. Ms. Cooper seconded and the motion passed unanimously.

Case No. 04-099A. Pharmacy permit holder allegedly sold a misbranded product as the result of a medication error. A prescription was presented for a 24 month old child for Sudal 12 ER suspension. The prescription was filled as Sudal liquid. The error was discovered by the pharmacist that evening upon reviewing his daily prescription activity. This is a relief pharmacist that did not have any technician help that day. The pharmacist notified the family of the error and delivered the corrected prescription. The child received one dose of the medication. Alleged violation of law: KRS 217.065(1). CRC recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Ms. Cooper seconded and the motion passed unanimously.

Case No. 04-099B. Pharmacist allegedly engaged in unprofessional conduct by committing a medication error. A prescription was presented for a 24 month old child for Sudal 12 ER suspension. The prescription was filled as Sudal liquid. The error was discovered by the pharmacist that evening upon reviewing his daily prescription activity. This is a relief pharmacist that did not have any technician help that day. The pharmacist notified the family of the error and delivered the corrected prescription. The child received one dose of the medication. Alleged violation of law: KRS 315.121(2)(d). CRC recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the

issuance of a Formal Complaint and Notice of Hearing. Ms. Cooper seconded and the motion passed unanimously.

Case No. 04-100. Pharmacist allegedly engaged in unprofessional conduct by substituting a generic version of a brand name drug on a refill. Patient had been on Synthroid for 25 years. On August 13, 2004, the pharmacist convinced her to change from the brand to the generic levothyroxine and she agreed. She had difficulty with the generic and informed one of her physicians, but not the physician that prescribed the Synthroid. The physician telephoned the pharmacist and requested brand for the patient. There was no documentation on paper or in the computer of this request for brand. A second pharmacist refilled the prescription on September 13, 2004, with the generic because there was no documentation in the computer not to do so. The patient returned with the generic and the second pharmacist did exchange the generic for the brand Synthroid. Alleged violation of law: KRS 315.121(2)(d). CRC recommendation: Case is dismissed. Ms. Cooper seconded and the motion passed unanimously.

Case No. 04-101A. Pharmacy permit holder allegedly sold a misbranded product as the result of a medication error. The Board office received a Medical Malpractice Payment Report from the pharmacy corporation. A prescription had been presented for Cortisporin Ophthalmic suspension. The prescription was dispensed as Cortisporin Otic suspension. The patient placed one drop of the otic suspension in her eye and it started burning. Alleged violation of law: KRS 217.065(1). CRC recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Ms. Cooper seconded and the motion passed unanimously.

Case No. 04-101B. Pharmacist engaged in unprofessional conduct by committing a medication error. The Board office received a Medical Malpractice Payment Report from the pharmacy corporation. A prescription had been presented for Cortisporin Ophthalmic suspension. The prescription was dispensed as Cortisporin Otic suspension. The patient placed one drop of the otic suspension in her eye and it started burning. Alleged violation of law: KRS 315.121(2)(d). CRC recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Ms. Cooper seconded and the motion passed unanimously.

Case No. 04-102. Pharmacy permit holder allegedly failed to have a pharmacist-in-charge (PIC) for nearly a two month period. On September 27, 2004, the Board received written notification that the PIC was departing. On November 22, 2004, the inspector received verbal confirmation that a new PIC was designated on November 22, 2004. Alleged violation of law: KRS 315.121(2)(d). CRC recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is

directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Ms. Cooper seconded and the motion passed unanimously.

Case No. 04-103. Pharmacy permit holder allegedly failed to have a pharmacist-in-charge (PIC) for approximately 84 days. On September 11, 2004, the Board office received written correspondence from the PIC stating that she was no longer PIC as of September 1, 2004. On November 10, 2004, the Board office received written correspondence that a new PIC had been designated. Alleged violations of law: KRS 315.020(1) and 201 KAR 2:205. CRC recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Ms. Cooper seconded and the motion passed unanimously.

Case No. 04-104. Pharmacist was disciplined by the Ohio Board of Pharmacy for practicing pharmacy without a license. Pharmacist licensed had expired and he continued to practice pharmacy for 7 days without a current license. Pharmacist is currently licensed in the Commonwealth of Kentucky. Alleged violation of law: KRS 315.121 (1)(c)3. CRC recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Ms. Cooper seconded and the motion passed unanimously.

CORRESPONDENCE: **Industrial Clerkship Approval/Allison Cooper.** The Board reviewed correspondence requesting a non-pharmacist be approved as a preceptor for a clerkship rotation at the pharmaceutical manufacturer Cardinal Health in Winchester, Kentucky. Ms. Cooper states that the date of the rotation is October 24, 2004 to November 21, 2004. Mr. Naseman moved that the pharmacist on staff at the manufacturer be designated as the preceptor and for the dates of the rotation to be verified. Mr. Edwards seconded and the motion passed unanimously.

LEGISLATION/REGULATIONS: **Statute Changes.** Mr. Naseman moved to approve the following draft statute changes and to bring these changes to a sponsor in the Kentucky Legislature:

KRS 315.120 Notification of failure to renew license – Procedure for renewal of expired license – Renewal after lapse of five or more years – Inactive license. Removal of the second and third sentences in (1) – ~~Failure to comply within sixty (60) days after notification shall result in automatic revocation of the license, unless the pharmacist is able to demonstrate by written petition at a hearing before the board that the failure to renew was not willful. The license holder shall be advised of this in the notification.~~

KRS 315.110 Renewal fee – Application and requirements – Certificate – Display – Pocket Certificate. Addition of first sentence in (1) – Each license to practice pharmacy, unless sooner suspended or revoked, shall expire on February 28 following its date of issuance. Removal of the second to last sentence in (1) – ~~The renewal fee and renewal period shall be set by administrative regulation of the board.~~ Change of the last sentence in (1) to read – A delinquent renewal penalty fee not to exceed the renewal fee may be assessed for each renewal period the licensee fails to renew the license [within thirty (30) days] after expiration.

KRS 315.035 Permit required for operation of a pharmacy – Application – Fee – Issuance – Fee for failure to renew – Premises covered by permit – Rules and regulations. Change of the last sentence in (4) to read: An additional fee not to exceed the annual renewal fee may be assessed as a delinquent renewal penalty for failure to renew by June 30 [August 1] of each year.

KRS 315.126 Impaired pharmacist committee – Administrative regulations – Assessment – Confidentiality – Reporting restrictions. Change the Impaired Pharmacist Committee to the Pharmacist Recovery Network.

Ms. Jones seconded and the motion passed unanimously.

CONTINUING EDUCATION: Mr. Edwards moved to accept the continuing education programs 04-036 through 04-041 as recommended. Mr. Naseman seconded and the motion passed unanimously.

FINES: Ms. Cooper moved to refer to case numbers only and not names in the fines report. Ms. Thornbury seconded and the motion passed unanimously.

OLD BUSINESS: **A. Technician Registering/Licensing Issue-Statute/Regulations.** After a brief discussion it was decided that Mr. Burleson is to begin collecting data from other states that register/license technicians and that this issue will be directed to the Advisory Council.

B. Internet Prescription Issue. This issue was not discussed because the information expected had not been received.

C. Telepharmacy Regulations. Mr. Burleson has requested the transcript from the March 2002 Board meeting so that the current Board members can review the decision.

D. Electronic Signatures. Mr. Burleson has sent a letter to WebMD clarifying that their electronic signatures are acceptable.

NEW BUSINESS: The Board of Pharmacy web site should go live by the first of 2005.

Ms. Thornbury moved for approval of the MARS information sheet to be included in the New Board Member Manual. Ms. Jones seconded and the motion passed unanimously.

Mr. Edwards presented President Armstrong with the Past President's Pin and informed President Armstrong that a donation was given to the University of Kentucky College of Pharmacy in his name.

ADJOURNMENT: On motion by Mr. Naseman and seconded by Ms. Cooper and passed unanimously, President Armstrong adjourned the meeting at 12:50 p.m. The next Board meeting is scheduled to begin at 9:00 a.m. on January 5, 2005 at the Board office in Frankfort.

Michael Burleson, Executive Director

MB:nkb